

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION**

NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,
MITSUBISHI TANABE PHARMA
CORPORATION, and MITSUI SUGAR CO.,
LTD

Plaintiffs,

v.

EZRA VENTURES, LLC

Defendants.

Civil Action No. 4:15-cv-00095-KGB

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR
MOTION TO STAY THE SECOND-FILED CASE
IN THE EASTERN DISTRICT OF ARKANSAS**

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I. INTRODUCTION

Plaintiffs brought suit in this District on February 13, 2015, for infringement of a patent covering Gilenya[®], the first FDA-approved oral medication to treat multiple sclerosis. The suit was prompted by a letter from Defendant stating that it had filed an Abbreviated New Drug Application (“ANDA”) with the FDA seeking approval to market a generic version of Gilenya[®] before the expiration of Plaintiffs’ patent rights. This is the second of two suits by Plaintiffs related to the same patent and same proposed generic product. The first suit was filed in Delaware on February 11, 2015. *Novartis AG, et al. v. Ezra Ventures LLC*, No. 15-00150-LPS (D. Del.) (“Delaware Action”).

The purpose of this second-filed action was to protect Plaintiffs’ rights should the Delaware court grant Defendant’s personal jurisdiction challenge. But, on May 11, 2015, the Delaware court held that it had jurisdiction over Defendant (Delaware Action at Oral Order, D.I. 27), and further ordered the parties hold a 26(f) conference and proceed with discovery immediately. *Id.* at Oral Order, D.I. 28. With the finding of jurisdiction in Delaware, this case can now be stayed (or administratively closed) pending resolution of the Delaware case. Plaintiffs sought Defendant’s consent to stay this action, but Defendant refused. Defendant’s refusal is improper.

It is black-letter law that cases should proceed in the first-filed forum when multiple lawsuits involving the same claims are filed in different jurisdictions. *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1299 (Fed. Cir. 2012). Here, the parties and issues are substantively identical to those in the first-filed Delaware case. A stay will avoid duplicative litigation, reduce expenses, and conserve judicial resources.

Nevertheless, Defendant refuses a stay because it disagrees with the Delaware court’s order regarding jurisdiction, plans to appeal it, and may refile its motion pending the Federal

Circuit's resolution of a similar jurisdictional dispute in an unrelated case. But that is not a basis for departing from the first-to-file rule. Indeed, Plaintiffs are not aware of any case where a second-filed court denied a stay after the first-filed court had already found jurisdiction. Therefore, this court should follow the first-to-file rule and stay the action.

II. PROCEDURAL AND FACTUAL BACKGROUND

This case concerns the infringement of a patent covering the active ingredient in Gilenya[®], the first orally-administered drug approved to treat multiple sclerosis.¹ See E.D. Ark. Compl. (D.I. 1), ¶ 14. On January 2, 2015, Defendant Ezra Ventures, LLC ("Ezra") informed Plaintiffs that it had filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking permission to market a generic version of Gilenya[®]. *Id.* at ¶ 18. Ezra's ANDA included a Paragraph IV certification, alleging that the Gilenya[®] patent was invalid, unenforceable, or not infringed by Ezra's proposed generic drug product. *Id.* at ¶ 19.

In accordance with the Hatch-Waxman Act, Plaintiffs filed suit against Ezra in the District of Delaware on February 11, 2015.² Ex. 1, Delaware Action at D.I. 1. The suit against Ezra is the third of three cases filed in Delaware involving the same patent and similar proposed generic products. See also *Novartis AG, et al. v. Actavis Inc., et al.*, No. 14-01487-LPS (D. Del.); *Novartis AG, et al. v. HEC Pharm. Group, et al.*, No. 15-00151-LPS (D. Del.).

Two days later, on February 13, 2015, Plaintiffs also filed suit against Ezra in this Court. E.D. Ark. Compl. (D.I. 1). The purpose of this second-filed action was to protect Plaintiffs'

¹ Plaintiffs Mitsubishi Tanabe Pharmaceutical Corporation and Misui Sugar Co., Ltd. own the patent-in-suit and have licensed it to Plaintiffs Novartis AG and Novartis Pharmaceuticals Corp. E.D. Ark. Compl. (D.I. 1), ¶ 13.

² Plaintiff Novartis Pharmaceutical Corporation is incorporated in Delaware. E.D. Ark. Compl. (D.I. 1), ¶ 3.

rights should the first case be dismissed for lack of personal jurisdiction. In particular, the Hatch-Waxman Act provides a statutory 30-month stay of regulatory approval of a proposed generic drug while patent litigation is pending. *See* 21 U.S.C. § 355(j)(5)(B)(iii). It is unclear, however, whether that regulatory stay is available if the litigation is dismissed for lack of personal jurisdiction. Accordingly, out of abundance of caution, Plaintiffs filed suits in Delaware, its preferred forum, and Arkansas.³

On April 2, 2015, Ezra moved to dismiss the first-filed Delaware case for lack of personal jurisdiction.⁴ Ezra's motion was the latest in a line of motions filed in courts across the country in the wake of the Supreme Court's decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (U.S. 2014). Ezra's motion, like those of several before it, was denied by the Delaware court on May 11, 2015.⁵ Delaware Action at Oral Order, D.I. 27. In so doing, the Delaware court

³ The purpose of the 30-month stay period is to provide the parties sufficient time to resolve any patent disputes before the generic ANDA product is commercially launched. Although Plaintiffs are not aware of any court that has terminated a 30-month stay based on lack of personal jurisdiction, and the relevant statute does not specify lack of personal jurisdiction as a ground to terminate the stay, Plaintiffs would risk significant, irreparable harm if they lost the 30-month stay. To guard against this risk, Hatch-Waxman plaintiffs often file a "protective suit" in a jurisdiction where the ANDA filer is unequivocally subject to general jurisdiction. Such suits are precautionary measures only, and are typically dismissed once personal jurisdiction over the defendants in the first-filed case has been confirmed. The instant action is precisely this type of protective suit.

⁴ Ezra also moved, in the alternative, to transfer the Delaware case to the Eastern District of Arkansas. *See* Ex. 2, Delaware Action, Ezra Ventures, LLC's Motion to Dismiss for Lack of Jurisdiction Over the Person, dated April 2, 2015 (D.I. 13). (Although Ezra's motion asks the Court to transfer the case to the District of New Jersey, Ezra's brief (Ex. 3, D.I. 14) asks the Court to transfer to Arkansas.)

⁵ *See Acorda Therapeutics, Inc., et al. v. Mylan Pharm., Inc., et al.*, C.A. No. 14-935-LPS, 2015 WL 186833, --- F. Supp. 3d --- (D. Del. Jan. 14, 2015); *AstraZeneca AB v. Mylan Pharm., Inc.*, C.A. No. 14-696-GMS, 2014 WL 5778016, --- F. Supp. 3d --- (D. Del. Nov. 5, 2015); *Forest Labs., Inc., et al. v. Amneal Pharm., et al.*, C.A. No. 14-508-LPS, D.I. 108 (D. Del. filed April 21, 2014), report and recommendation adopted, C.A. No. 14-508-LPS, 2015 WL 1467321 (D. Del. March 30, 2015); *Novartis Pharm. Corp., et al v. Mylan Inc., et al.*, C.A. No. 14-777-RGA, 2015 WL 1246285 (D. Del. Mar. 16, 2015); *Eli Lilly and Co., et al. v. Mylan Pharm., Inc., et al.*, C.A. No. 14-389-SEB-TAB, 2015 WL 1125032, --- F. Supp. 3d --- (S.D. Ind. Mar. 12, 2015); *Allergan, Inc. v. Actavis, Inc., et al.*, C.A. No. 14-638-JRG, 2014 WL 7336692 (E.D. Tex. Dec. 23, 2014).

permitted Ezra to “renew after the Federal Circuit Court of Appeals issues its decision in the pending interlocutory appeals that will likely address similar if not identical matters as presented by Defendant’s motion.”⁶ *Id.* That same day, the Delaware court ordered the parties to participate in a Rule 26(f) conference by May 29, 2015. *Id.* at Oral Order, D.I. 28. The parties held that conference on May 21, 2015.

This second-filed case is in its nascent stages. No initial disclosures have been exchanged; no discovery requests have been served; and no depositions have been taken.

III. ARGUMENT

A. The Court Should Stay This Case Under the First-to-File Rule

The first-to-file rule is an equitable doctrine that aims to avoid duplicative litigation.⁷ *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1299 (Fed. Cir. 2012) (“The ‘first-to-file’ rule is a doctrine of federal comity, intended to avoid conflicting decisions and promote judicial efficiency, that generally favors pursuing only the first-filed action when multiple lawsuits involving the same claims are filed in different jurisdictions.”) (citations omitted); *see also Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993). Under the first-to-file rule, when two courts have concurrent jurisdiction over substantially identical cases, the court hearing the second-filed case should defer to the court of first-filing, for example, by staying or

⁶ The Federal Circuit has certified interlocutory appeal of decisions regarding personal jurisdiction in Hatch-Waxman patent infringement in two proceedings unrelated to the instant case. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, No. 15- 124, D.I. 21 (Fed. Cir. Mar. 17, 2015) (“Acorda”); *AstraZeneca AB v. Mylan Pharm. Inc.*, No. 15-117, D.I. 31 (Fed. Cir. Mar. 17, 2015) (“AstraZeneca”). The date by which these appeals will be decided is unknown.

⁷ The application of the first-to-file rule to this case is governed by Federal Circuit law. *See, e.g., Genentech*, 998 F.2d at 937; *J.P. Sercel Assocs., Inc. v. New Wave Research*, No. 03-331-JD, 2003 WL 22299014, at *1 (D.N.H. Oct. 7, 2003) (“[D]istrict courts follow Federal Circuit precedent in considering the first-filed action rule in patent cases.”). For aspects of the first-to-file rule on which the Federal Circuit has been silent, “district courts look to understandings of the doctrine as developed generally in the federal courts.” *Shire U.S., Inc. v. Johnson Matthey, Inc.*, 543 F. Supp. 2d 404, 408 (E.D. Pa. 2008).

transferring the second-filed case. *Merial Ltd.*, 681 F.3d at 1299. Courts consider several factors in determining whether the first-to-file rule applies: (1) chronology of the two cases; (2) similarity between the parties; and (3) similarity between the issues. *See, Furminator, Inc. v. Munchkin, Inc.*, No. 4:08-cv-00367-ERW, 2009 U.S. Dist. LEXIS 82350, *7-8 (E.D. Mo. Sept. 10, 2009).

Given these criteria, application of the first-to-file rule is appropriate here. *First*, the complaint in this case was filed two days later than the complaint filed in the Delaware case. *Second*, the parties involved in this case and the Delaware case are identical. *Third*, the “similarity of issues” prong is satisfied because the claims in both complaints are identical. Indeed, courts in this district have applied the first-to-file rule where – as here – many of the same witnesses will have to testify, much of the same documentary evidence will have to be presented, and the two different district courts will be applying the same body of law to resolve the same type of dispute. *Nelson Design Group, LLC v. Frank Betz Assocs.*, No. 3:06-cv-00061-GTE, 2006 U.S. Dist. LEXIS 99305, *3-4 (E.D. Ark. Aug. 9, 2006).

Many courts have also applied the first-to-file rule in cases involving a second “protective suit” brought under the Hatch-Waxman Act. For example, in *Pfizer, Inc. v. Mylan, Inc.*, Pfizer sued Mylan in Delaware for the alleged infringement of patents covering one of Pfizer’s drugs. *See*, No. 1:09-cv-79, 2009 U.S. Dist. LEXIS 124954, at *1 (N.D. W. Va. Nov. 20, 2009). Later that same day, Pfizer filed a “nearly identical” complaint against Mylan in the Northern District of West Virginia, “as a hedge against the risk of dismissal for want of jurisdiction.” *Id.* at 1-3. In granting a motion to transfer the case to Delaware, the West Virginia court found that, on the facts of that case, application of the first-to-file rule would “promot[e] uniformity of results, avoid[] duplicative litigation, and conserv[e] scarce judicial resources.” *Id.*

at 7-8. *See also Pfizer Inc. v. Apotex Inc.*, 640 F. Supp. 2d 1006, 1010-11 (N.D. Ill. 2009) (staying a protective suit pending the resolution of a jurisdictional dispute in the first-filed case because of the “obligation to avoid duplicative litigation, the inevitable waste of judicial and party resources that will result if both this action and the identical Delaware action proceed, and [the] conclusion that a slight delay will not cause Apotex undue prejudice”); *Schering Corp. v. Caraco Pharm. Labs., Ltd.*, No. 06-cv-14386, 2007 WL 1648908, at *3 (E.D. Mich. June 6, 2007) (staying a protective suit pending the resolution of a jurisdictional dispute in the first-filed case because of “the probable inefficiency and the potential for the misuse of the limited resources of the judiciary that would occur if this [second-filed] litigation moved forward”); *PDL Biopharma, Inc. v. Sun Pharm. Indus., Ltd.*, No. 07-cv-11709, 2007 WL 2261386, at *2-3 (E.D. Mich. Aug. 6, 2007) (staying a protective suit pending the resolution of a transfer dispute in the first-filed case, noting that “[a]llowing two identical suits to proceed in a parallel manner would clearly be contrary to the principles of comity and would waste scarce judicial resources”); *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, No. 1:07-cv-993, 2007 WL 4284877, at *2-3 (W.D. Mich. Dec. 3, 2007) (staying a protective suit pending the resolution of a transfer dispute in the first-filed case because “equity compels the Court to grant [plaintiff’s] motion to stay in favor of the first-filed case”).

Departure from the first-to-file rule requires a “sound reason that would make it unjust or inefficient to continue the first-filed action.” *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 938 (Fed. Cir. 1993) *abrogated on other grounds*, *Wilton v. Seven Falls Co.*, 515 U.S. 277 (1995). Plaintiffs anticipate that Ezra will contend that jurisdiction is “unsettled” in Delaware, thus making it appropriate to proceed with the case in this forum. *See e.g., Genentech*, 998 F.2d

at 938 (listing the absence of jurisdiction as a “sound reason that would make it unjust or inefficient to continue the first-filed action.”). Ezra is wrong.

Jurisdiction is not unsettled in Delaware. The Delaware court has ruled that it has jurisdiction over Ezra. The result is consistent with every other district court that has had to consider such jurisdictional arguments from generic drug manufacturers post-*Daimler*. See *supra* at n.4. Plaintiffs are not aware of a single case where a second-filed court refused to grant a stay based on allegedly “unsettled” jurisdiction after the first-filed court had already found jurisdiction. This is unsurprising, as denying a stay in these circumstances would undermine the principle of comity that forms the basis of the first-to-file rule. Ezra’s unhappiness with the Delaware court’s decision does not create an “unsettled” issue and is not a basis for departure from the first-to-file rule. As another court recently found in granting a motion to stay a second-filed case in a nearly identical situation, “any other ruling would imply that district courts should defer only to appellate decisions, thereby vitiating the first-to-file rule and rejecting its central premise—deference to the first-filed jurisdiction under the principle of comity.” Ex. 4, *Novartis Pharms. Corp. et al. v. Mylan Inc. et al.*, No. 14-111-IMK (N.D. W.Va.), Order Granting Plaintiffs’ Renewed Motion to Stay (D.I. 75) at p. 10; see also Ex. 5, *Pfizer Inc. et al. v. Mylan Inc. et al.*, No. 15-4-IMK (N.D. W.Va.), Order Granting Plaintiffs’ Motion to Stay the Second-Filed Suit and Staying the Case (D.I. 41) at pp. 10-11; *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, No. 07-993-GJQ, 2007 U.S. Dist. LEXIS 88556, at *2 (W.D. Mich. Dec. 3, 2007).

None of the remaining exceptions to the first-to-file rule applies here either. Such exceptions include a consideration of whether the “balance of convenience” weighs in favor of the second-filed court’s continued exercise of jurisdiction over the second-filed suit, or whether

specific “compelling circumstances” favor the second-filed court’s jurisdiction.⁸ *See Brower v. Flint Ink Corp.*, 865 F. Supp. 564, 567-68 (N.D. Iowa 1994). Ezra cannot show that the balance of convenience “strongly favors” jurisdiction in this court. *Ray v. Am. Airlines, Inc.*, No. 08-5025, 2008 U.S. Dist. LEXIS 42998, *17 (W.D. Ark. June 2, 2008). Indeed, a plaintiffs’ choice of forum is given “great weight” and should “rarely be disturbed.” *Id.* at *19. This is particularly true where, as here, the plaintiff is organized and exists under the laws of the state of the first-filed action. *Id.* at *19-20.

Nor are the two factual “compelling circumstances” allowing for exception to the first-to-file rule present. As other courts have found, the filing of a “protective suit” in the Hatch-Waxman context is not an act of bad faith or improper forum shopping. *Pfizer*, 2009 U.S. Dist. LEXIS 124954, at *6. Nor is the present action a continuation or enforcement of a legal process already started in this court. Rather, this case presents the ‘textbook’ scenario for application of the first-to-file rule: when two separate but identical actions have been filed in two different district courts, the forum of the first-filed case is given priority over the second-filed forum.

B. Additional Considerations Weigh in Favor of a Stay

Even in the absence of the first-to-file rule, district courts have broad discretion to stay proceedings when the nature and stage of a case favors a stay. *See e.g., Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936); *Clinton v. Jones*, 520 U.S. 681, 706-07 (1997). Relevant factors in determining whether a stay is appropriate include “(1) potential prejudice to the non-moving

⁸ “The Eighth Circuit Court of Appeals has recognized two specific factual circumstances in which it will find an exception to the ‘first-filed’ rule and allow the second suit to continue: (1) where the plaintiff in the first-filed action was able to file first only because it had misled the filer of the second-filed action as to its intentions regarding filing suit in order to gain the advantages of filing first; and (2) where the second-filed action is a continuation of a legal process already begun in that court even though another action concerning the same issues has been filed in between in another court and is therefore ostensibly the first-filed action.” *Brower*, 865 F. Supp. at 569.

party; (2) hardship and inequity to the moving party if the matter is not stayed; and (3) economy of judicial resources.” *Lopez v. Tyson Foods, Inc.*, No. 8:06-cv-459, 2008 U.S. Dist. LEXIS 106132, *5-6 (D. Neb. Sept. 8, 2008). Here, each of these factors weighs in favor of a stay.

First, granting a stay will halt wasteful parallel litigation, saving resources for the judiciary and both parties. Indeed, there can be no real dispute that a stay will promote the “economy of judicial resources.”

Second, proceeding in Delaware will not cause Ezra undue hardship. Plaintiffs anticipate that Ezra will suggest that litigation in Delaware would be wasted if the Federal Circuit later reverses in *AstraZeneca* or *Acorda*. But the Delaware court has already determined that it has jurisdiction over Ezra. If a Federal Circuit decision in the unrelated cases makes clear that there is no jurisdiction in Delaware, the Delaware court could easily transfer the case at that time to this District. *See Forest Laboratories Inc. v. Cobalt Laboratories Inc.*, C.A. No. 08-21-GMS-LPS, 2009 WL 605745, *12 n.10 (D. Del. Mar. 9, 2009), report and recommendation adopted, C.A. No. 08-21-GMS-LPS, 2009 WL 2753427 (D. Del. Dec. 11, 2009) (transferring a Hatch-Waxman case under 28 U.S.C. §§ 1406 and 1631 after finding a lack of personal jurisdiction over the defendants). This Court would then be free to accept or reject the Delaware court’s decisions as it sees fit. *Cf. Wilson v. Turnage*, 755 F.2d 967, 967-68 (D.C. Cir. 1985) (vacating its prior decision on the merits due to a lack of jurisdiction and transferring the case to the Federal Circuit, while noting that “it may not be necessary for the Federal Circuit to reconsider the merits of our opinion. When cases are transferred between courts of coordinate jurisdiction or different judges of the same court, for example, the prior rulings of the transferor court or judge are generally followed in the interests of judicial economy.”) (citations omitted).

Third, if this case is not stayed, Plaintiffs will suffer significant hardship. Plaintiffs will be forced to litigate two identical cases, seeking the same relief in two district courts. This will require duplicative effort and expense that is unnecessarily wasteful, whereas a stay will “save judicial resources.” *Petonyak Mach. Corp. v. Brandt Indus.*, No. 4:10-cv-00772-JMM, 2011 U.S. Dist. LEXIS 4113, *2 (E.D. Ark. Jan. 13, 2011). If this case proceeds while the Delaware case is pending, there is a substantial risk that the Court and the parties will expend considerable time and resources litigating essentially identical issues. *See e.g., Nelson Design Group*, 2006 U.S. Dist. LEXIS 99305, at *3-4 (noting that a second, parallel litigation would result in “a significant amount of duplicative effort, unnecessary expense, and waste of judicial resources”). A stay is appropriate on the facts of this case.

IV. CONCLUSION

For the reasons set forth above, Plaintiffs respectfully requests that this Court stay (or administratively close) this second-filed case pending resolution of the Delaware Action.

DATED: May 22, 2015

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CERTIFICATE OF SERVICE

I, Clifford W. Plunkett, hereby certify that on May 22, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all counsel of record.

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